

# In the United States Court of Federal Claims

No. 00-745V

Filed: October 1, 2008

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**RUBY HOPKINS, a minor, by her  
parents and natural guardians, GREG  
HOPKINS and HELEN HOPKINS,**

**Petitioners,**

**v.**

**SECRETARY OF THE DEPARTMENT  
OF HEALTH AND HUMAN SERVICES,**

**Respondent.**

\* \* \* \* \*

**Motion for Review of Special  
Master's Decision; National Vaccine  
Compensation Act, 42 U.S.C. §§  
300aa-1 – 300aa-34.**

**Clifford J. Shoemaker**, Shoemaker and Associates, Vienna, Virginia, for the petitioner.

**Lisa A. Watts**, Trial Attorney, Torts Branch, Civil Division, United States Department of Justice, Washington, D.C., for the respondent. With her were **Jeffrey S. Bucholtz**, Acting Assistant Attorney General; **Timothy P. Garren**, Director; **Vincent J. Matanoski**, Acting Deputy Director; and **Catharine E. Reeves**, Assistant Director, Torts Branch, Civil Division, United States Department of Justice, Washington, D.C.

## OPINION

**HORN, J.**

## PROCEDURAL HISTORY AND FINDINGS OF FACT

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<sup>1</sup> This opinion was issued under seal on October 1, 2008. Petitioner and respondent were given the opportunity to propose redactions to the opinion, but did not propose redactions. The opinion, therefore, is unsealed without redactions.

On December 11, 2000, petitioners Greg and Helen Hopkins, acting on behalf of their daughter Ruby, filed a petition seeking compensation under the National Vaccine Injury Compensation Act, 42 U.S.C. §§ 300aa-1 – 300aa-34 (2000) (Vaccine Act). Petitioners allege that Ruby suffered bilateral sensorineural hearing loss as a result of haemophilus influenzae type B (“HIB”), diphtheria-tetanus-pertussis (“DTP”), and oral polio (“OPV”) vaccinations received on December 10, 1998. Also on December 11, 2000, these same individuals, this time acting on behalf of their other child, Finn Hopkins, filed a separate claim, also for bilateral sensorineural hearing loss as a result of the HIB, DTP and OPV vaccinations, likewise received on December 10, 1998. Chief Special Master Gary Golkiewicz chose to hold a single hearing for both children and issued a single decision in the two separately filed cases. According to the Chief Special Master, the petitioners in both the cases were in agreement on how to proceed.

The Chief Special Master held a factual hearing on September 27, 2004, at which both parents testified as fact witnesses. The Chief Special Master concluded that, Ruby’s hearing loss was not noticed until the night of January 1, 1999, approximately three weeks following her immunizations. On February 9, 2007, the Chief Special Master issued a “Factual Determination,” in which he found “petitioners’ testimony to be credible in noting the onset of Ruby’s hearing loss after receiving the December 10, 1998 vaccinations.” He, therefore, ordered the parties to notify him as to how they intended to proceed. Subsequently, however, after hearing testimony from respondent’s experts, particularly, Dr. Leila Mankarious, the Chief Special Master appears to have reversed himself on the timing issue with respect to Ruby, as is discussed more fully below. In addition to the summary contained in this opinion, a more extensive presentation of the facts of Ruby’s medical history is found in the Chief Special Master’s Decision on Remand.

On August 10, 2007, after reviewing the record, including the testimony of fact and expert witnesses and the submitted documentary evidence, the Chief Special Master issued a single opinion denying entitlement to both Ruby and her brother Finn. Ruby Hopkins and Finn Hopkins ex rel. Greg and Helen Hopkins v. Sec’y of HHS, Nos. 00-745V and 00-746V, 2007 WL 2454038 (Fed. Cl. Aug. 10, 2007). Petitioners filed a motion for review of the Chief Special Master’s decision on September 9, 2007. The final single opinion issued by the Chief Special Master stated that: “[t]hroughout the presentation of these cases, the two cases had been treated essentially as one.” Based on the decision to treat the two cases together, the Chief Special Master also indicated, “the presentation of the two cases are so intertwined through the expert testimony, it makes eminent sense to resolve the cases through one opinion.”

This court recognizes that combining the two cases might produce ease, speed and cost reduction. Moreover, from petitioners’ point of view, combining the cases would enable the petitioners to use one case to bolster the other, specifically using the case of Ruby Hopkins to strengthen that of Finn Hopkins. This court, however, disagreed with the decision to treat the two cases, which put at issue distinct medical facts, of two separate physical beings, of different ages, as one entity. Although the

Chief Special Master acknowledged some differences between Ruby and Finn in his single opinion, upon reading the opinion of the Chief Special Master, this court was concerned that too much information had been merged and too little consideration given to possible different conclusions. Therefore, on October 16, 2007, this court remanded the two separately filed cases to the Chief Special Master for separate consideration of each child's case. In doing so, this court noted, respecting the two separate cases, that "while the facts share some similarities, they are not identical," and "that separate opinions should have been issued in each case." This court also directed that, "[a]s part of the remand consideration, the [Chief] Special Master shall give consideration to whether sufficient facts exist in the current record to enable him to reach an independent conclusion as to each child." The Chief Special Master also was instructed that if he did not hold further hearings, he "should indicate his reasons for doing or not doing so in his final opinion."

The Chief Special Master did not hold additional hearings or take any additional evidence. On December 14, 2007, the Chief Special Master issued two Decisions on Remand, one for Ruby Hopkins and one for Finn Hopkins. Neither decision contained substantive changes to the original single opinion. The primary difference between the original and the Remand Decisions was that the Chief Special Master's discussion and conclusion was segregated into one opinion for Ruby and one for Finn. In fact, in the Chief Special Master's decision after the remand, he specifically wrote, "[t]he undersigned notes for the convenience of the court and the parties that in issuing this separate decision for Ruby Hopkins, no substantive changes were made to the undersigned's initial Decision [the Joint Decision issued earlier]." Ruby Hopkins v. Sec'y of HHS, No. 00-745, slip op. at 3 (Fed. Cl. Spec. Mstr. Dec. 14, 2007). In the case of Ruby Hopkins, discussed in this opinion, the Chief Special Master concluded that based on the record, she was not entitled to compensation under the Vaccine Act. On January 7, 2008, petitioners filed a motion for review of the December 14, 2007 Remand Decision.

Ruby was born on November 23, 1994. Ruby's first documented pediatric visit was to John Caeton, M.D., on December 28, 1995, who diagnosed her with bronchiolitis.<sup>2</sup> Ruby returned to Dr. Caeton on March 3, 1996 after vacationing in Mexico. Her parents reported that she had been sick for 10-12 days with "occasional fever as high as 105.6 [degrees]." Dr. Caeton's diagnosis was "Suspect pneumonia. Also Otitis [inflammation of the middle ear]."

Ruby returned to Dr. Caeton on July 19, 1996 and began her series of recommended childhood immunizations, at which time she received an oral Polio vaccine (OPV) and Tetramune (a combination vaccine for diphtheria, tetanus, pertussis (DTP) and haemophilus influenzae type B (HIB)).<sup>3</sup> Based on the record, Ruby appears

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<sup>2</sup> According to the record, this was the first time Ruby was seen by a pediatrician.

<sup>3</sup> Ms. Hopkins, Ruby's mother, referred to vaccines as "toxins made from diseases."

to have had no adverse reaction to this first series of immunizations. A "Deployment/Travel Medicine Questionnaire," dated December 9, 1998, identifying Ruby as the patient, notes proposed recreational travel to Thailand. Following visits to Dr. Caeton for viral gastroenteritis and bilateral conjunctivitis, on December 10, 1998, Ruby again was administered the HIB/DTB and OPV vaccines at Elmendorf Air Force Base. Petitioners' claim is predicated upon a reaction to this second set of vaccines administered in December 1998.

On January 4, 1999, Ruby's medical records indicate that she was seen at the Pediatric Clinic for "[p]erceived hearing loss." The report indicated "no risk factors" and that Ruby's speech was "O.K." The physical examination revealed "clear & mobile" tympanic membranes ("TM"). An audiology consult was recommended. Ruby again received Tetramune and OPV vaccines on January 11, 1999.

On January 12 and 18, 1999, Ruby underwent a series of audiological evaluations. According to Ruby's medical records, Mr. and Mrs. Hopkins reported that, "Ruby seemed to respond inconsistently, but they weren't sure at first if it was just 'selective hearing.'" The parents also reported that Ruby had stated that "her left ear 'didn't work'" and that there was other behavioral evidence indicating possible hearing loss in the left ear. During these audiological evaluations, testing revealed "a mild to possibly moderate, sensorineural hearing loss in her right ear, and a moderate, possibly severe sensorineural hearing loss in her left ear." According to the record, "[r]esults of tympanometry and acoustic reflex testing revealed normal middle ear function and presence of acoustic reflexes for both ears. . . . Results of OAE [otoacoustic hearing] testing revealed no measurable cochlear emissions which confirmed abnormal cochlear function (hearing loss) bilaterally." It was concluded that "the evaluations were consistent with a hearing loss for both ears." The medical report indicates that the results were discussed with Ruby's parents, including an explanation that, "the cause of Ruby's hearing loss may not be determined." It was suggested Ruby be fitted with hearing aids to assist her in hearing soft speech and that she "be seen by an Ear, Nose and Throat physician to rule out any medical concerns that may affect Ruby's hearing."

On January 20, 1999, Ruby was evaluated by Donald Endres, M.D., at an Ear, Nose, and Throat (ENT) clinic. Following the examination, the doctor stated that he could not "find anything in the history or physical examination pointing to a specific syndromic cause for this deafness." Two days later, on January 22, 1999, Ruby was seen by Randall Ow, M.D. Dr. Ow indicated that Ruby was referred to him after a hearing evaluation revealed significant hearing loss. Dr. Ow performed a physical evaluation and noted that Ruby's ears were normal as to externally observable causes for the hearing loss. He indicated that Ruby's hearing loss was probably congenital and suggested additional testing and consultation be performed.

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She, therefore, chose not to have Ruby vaccinated until she was eighteen months old.

On March 8, 1999, Ruby saw Dr. Caeton for a checkup. Dr. Caeton noted that Ruby had received immunizations in December 1998 and in January 1999, and that her parents had indicated her hearing seemed diminished. He also pointed out that recently she had been coughing and congested with intermittent fevers. His impression was that she had "hearing loss which sounds like it is neurological as opposed to related to middle ear dysfunction." Moreover, he indicated she "has a current otitis media" [inflammation of the middle ear].

On May 14, 1999, Ruby had a follow up appointment with Dr. Ow. Dr. Ow stated that, "[o]n detailed questioning regarding the patient's family history on the maternal side the grandmother's brother apparently was deaf as a child." He also commented that there was "a maternal uncle who had significant hearing loss before the age of 20 and also a maternal sister who has cerebral palsy with mild hearing losses." Dr. Ow noted, however, that Ruby's parents suspected that the hearing loss "may be related to the DPT/HIB vaccination performed in December 1998." Dr. Ow disagreed with Mr. and Mrs. Hopkins' assessment, noting that, "in light of the significant family history of probable hereditary hearing loss, is [sic] seems more likely that the child's condition represents a progressive hereditary sensorineural hearing loss."

On June 24, 1999, a deafness DNA screen was performed on Ruby at a genetics laboratory to test for mutations in the CX26 gene, which is associated with deafness. The results indicated that, "[n]o mutations were detected in the CX26 gene," but that, "[t]his is still consistent with a clinical diagnosis of autosomal recessive nonsyndromic deafness . . . because this test does not detect all possible mutations." A letter dated September 17, 1999 from Richard Smith, M.D., to Dr. Mark J. Stephan, Dr. Smith states:

The father and both hearing-impaired children [Ruby and her younger brother Finn] carry the M34T mutation in Connexin 26. Although the pathologic significance of this mutation has been debated in the literature, it is our opinion that the mutation represents a benign polymorphism and is not disease causing. Based on this interpretation, it is our opinion that your family does not have deafness due to mutations in Connexin 26. However, the history is still consistent with a clinical diagnosis of autosomal recessive non-syndromic hearing loss due to mutations in another gene.

On July 20, 1999, Ruby was evaluated for bilateral sensorineural hearing loss by Phillip Massengill, M.D., at an ENT Clinic at the Madigan Army Medical Center in Tacoma, Washington. Dr. Massengill noted that while he found no known etiology for the hearing loss, the risks and benefits of immunizations and temporal association of possible medical reactions from immunizations were discussed with the parents.

On July 23, 1999, Ruby and her brother Finn received comprehensive clinical genetics evaluations by Dr. Stephan. Ruby's patient history indicated that her parents

stated that she “babbled and began speaking words at the normal age and they considered her expressive speech to be completely normal at age 2 years.” The records indicate that following Ruby’s December 10, 1998 vaccinations, Ruby’s father found that beginning on January 1, 1999, Ruby was not responding to his voice.

In evaluating Ruby’s family history, Dr. Stephan noted that Ruby’s mother’s auditory evaluation “detected a very mild auditory deficit in the high frequency ranges only.” Dr. Stephan also noted that Mrs. Hopkins’ sister suffered from minor cerebral palsy and had a “minor auditory deficit.” In addition, it was noted that Mrs. Hopkins has one “paternal uncle who has hearing loss secondary to mastoiditis at age 4 as well as noise trauma” and “another paternal uncle with hearing loss associated with multiple bouts of otitis media.” It also was noted that Mrs. Hopkins “has a maternal uncle who had adult onset hearing loss and is also visually impaired.” Mr. Hopkins, however, had a normal hearing test, with Dr. Stephan noting that Ruby’s grandfather “has hearing loss of adult onset secondary to artillery noise.” Dr. Gerald Raymond, petitioners’ expert, however, indicated that no audiograms or evaluations were produced and, therefore, there is “no evidence that this hearing loss is also not genetic.” Dr. Stephan ultimately concluded that Ruby suffered from “[b]ilateral sensorineural [sic] hearing deficit.” With regards to the parents’ concern that Ruby and Finn’s hearing loss might be related to the immunizations received, Dr. Stephan noted that the condition “represents an autosomal recessive non-syndromic auditory deficit,” and that there were “no other previous reports of hearing loss developing after a DPT immunization . . . .” He further noted that Dr. Mary Fairchok of Pediatric Infectious Diseases also was not aware of any such reports or cases correlating DPT immunizations and hearing loss.

In a report, dated August 20, 1999, Dr. Thad Woodward conveyed the results of the genetic evaluations performed on Ruby and her brother Finn. He stated: “[i]t is certainly curious that both children have developed bilateral hearing loss within a short period of time after receiving DPT vaccine, and although I do not personally believe that this is the likely cause of the coincidental hearing loss, we do not have any other explanation.”

## **DISCUSSION**

When reviewing a special master’s decision, the assigned judge of the United States Court of Federal Claims shall:

- (A) uphold the findings of fact and conclusions of law of the special master and sustain the special master’s decision,
- (B) set aside any findings of fact or conclusions of law of the special master found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law and issue its own findings of fact and conclusions of law, or

(C) remand the petition to the special master for further action in accordance with the court's direction.

42 U.S.C. § 300aa-12(e)(2); see also Rules of the United States Court of Federal Claims (RCFC) App. B (Vaccine Rules) , Rule 27. The legislative history of the Vaccine Act states that, "[t]he conferees have provided for a limited standard for appeal from the [special] master's decision and do not intend that this procedure be used frequently, but rather in those cases in which a truly arbitrary decision has been made." H.R. Conf. Rep. No. 386, 101st Cong., 1st Sess. 512-13, 517, reprinted in 1989 U.S.C.C.A.N. 1906, 3115, 3120.

Regarding the standard of review, in Markovich v. Sec'y of HHS, the United States Court of Appeals for the Federal Circuit wrote, "[u]nder the Vaccine Act, the Court of Federal Claims reviews the Chief Special Master's decision to determine if it is 'arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law.' 42 U.S.C. § 300aa-12(e)(2)(B)." Markovich v. Sec'y of HHS, 477 F.3d 1353, 1355-56 (Fed. Cir.), cert. denied, 128 S. Ct. 92 (2007); see also Bazan v. Sec'y of HHS, 539 F.3d 1347, 1350 (Fed. Cir. 2008); Althen v. Sec'y of HHS, 418 F.3d 1274, 1277 (Fed. Cir. 2005).

As described by the Federal Circuit in Althen:

The [Vaccine] Act provides for the establishment of causation in one of two ways: through a statutorily-prescribed presumption of causation upon a showing that the injury falls under the Vaccine Injury Table ("Table injury"), see 42 U.S.C. § 300aa-14(a); or where the complained-of injury is not listed in the Vaccine Injury Table ("off-Table injury"), by proving causation in fact, see 42 U.S.C. §§ 300aa-13(a)(1), -11(c)(1)(C)(ii)(I).

Althen v. Sec'y of HHS, 418 F.3d at 1278; see also Pafford v. Sec'y of HHS, 451 F.3d 1352, 1356 (Fed. Cir.), reh'g and reh'g en banc denied (Fed. Cir. 2006), cert. denied, 127 S. Ct. 2909 (2007).

Petitioners, on behalf of Ruby Hopkins, claim that as a result of the HIB, DPT and OPV vaccinations on December 10, 1998, Ruby suffered post-vaccinal bilateral sensorineural hearing loss (SNHL), and that a petitioner is entitled to compensation for an off-Table injury, with conditions and symptoms not listed on the Vaccine Injury Table. Under the off-Table theory of recovery, a petitioner is entitled to compensation if she can demonstrate by a preponderance of the evidence (42 U.S.C. § 300aa-13(a)(1)(A)), that the recipient of the vaccine sustained, or had significantly aggravated, an illness, disability, injury, or condition not set forth in the Vaccine Injury Table (42 U.S.C. § 300aa-14(a) and 42 C.F.R. § 100.3), but which was caused by a vaccine that is listed on the Vaccine Injury Table. 42 U.S.C. § 300aa-11(c)(1)(C)(ii)(I); see also Althen v. Sec'y of HHS, 418 F.3d at 1278; Hines ex rel. Sevier v. Sec'y of HHS, 940 F.2d 1518, 1525 (Fed. Cir. 1991).

Since Ruby's condition does not meet the requirements of a presumptively on-Table, vaccine-related condition, to prove entitlement for an off-Table injury, petitioners must:

prove causation-in-fact. Grant v. Sec'y of HHS, 956 F.2d [1144,] 1147-48 [(Fed. Cir. 1992)]. [The United States Court of Appeals for the Federal Circuit has] held that causation-in-fact in the Vaccine Act context is the same as the "legal cause" in the general torts context. Shyface v. Sec'y of Health and Human Servs., 165 F.3d 1344, 1352 (Fed. Cir. 1999). Therefore, drawing from the Restatement (Second) of Torts, the vaccine is a cause-in-fact when it is "a substantial factor in bringing about the harm."

Bazan v. Sec'y of HHS, 539 F.3d at 1351 (quoting the Restatement (Second) of Torts § 431(a)). A "substantial factor" standard requires a greater showing than 'but for' causation." Bazan v. Sec'y of HHS, 539 F.3d at 1351 (quoting Shyface v. Sec'y of HHS, 165 F.3d at 1352). "However, the petitioner need not show that the vaccine was the sole or predominant cause of her injury, just that it was a substantial factor." Bazan v. Sec'y of HHS, 539 F.3d at 1351.

When proving eligibility for compensation for an off-Table injury under the Vaccine Act, petitioners may not rely on their testimony alone. According to the Vaccine Act, "[t]he special master or court may not make such a finding based on the claims of a petitioner alone, unsubstantiated by medical records or by medical opinion." See 42 U.S.C. § 300aa-13(a)(1).

The petitioners must prove their case by a preponderance of the evidence. 42 U.S.C. § 300aa-13(a)(1)(A). According to the United States Court of Appeals for the Federal Circuit, the preponderance of evidence standard is "one of proof by a simple preponderance, of 'more probable than not causation.'" Althen v. Sec'y of HHS, 418 F.3d at 1279-80 (citing concurrence in Hellebrand v. Sec'y of HHS, 999 F.2d 1565, 1572-73 (Fed. Cir. 1993)). Decisions of the Federal Circuit permit the use of circumstantial evidence, which the court described as "envisioned by the preponderance standard," and by the vaccine system created by Congress in which "close calls" regarding causation are resolved in favor of injured claimants" without the need for medical certainty. Althen v. Sec'y of HHS, 418 F.3d at 1280. The Althen court further noted that "the purpose of the Vaccine Act's preponderance standard is to allow the finding of causation in a field bereft of complete and direct proof of how vaccines affect the human body." Id. (citing Knudsen v. Sec'y of HHS, 35 F.3d 543, 549 (Fed. Cir. 1994)).

In a comprehensive discussion, the court in Althen defined a three-prong test which a petitioner must meet to establish causation in an off-Table injury case:



To meet the preponderance standard, [petitioner] must “show a medical theory causally connecting the vaccination and the injury.” Grant v. Sec’y of Health & Humans Servs., 956 F.2d 1144, 1148 (Fed. Cir. 1992) (citations omitted). A persuasive medical theory is demonstrated by “proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury[.]” the logical sequence being supported by “reputable medical or scientific explanation[.]” i.e., “evidence in the form of scientific studies or expert medical testimony[.]” Grant, 956 F.2d at 1148. [Petitioner] may recover if she shows “that the vaccine was not only a but-for cause of the injury but also a substantial factor in bringing about the injury.” Shyface, 165 F.3d at 1352-53. Although probative, neither a mere showing of a proximate temporal relationship between vaccination and injury, nor a simplistic elimination of other potential causes of the injury suffices, without more, to meet the burden of showing actual causation. See Grant, 956 F.2d at 1149. Concisely stated, [petitioner’s] burden is to show by preponderant evidence that the vaccination brought about [the] injury by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury.

Althen v. Sec’y of HHS, 418 F.3d at 1278 (brackets added); see also Pafford v. Sec’y of HHS, 451 F.3d at 1355; Capizzano v. Sec’y of HHS, 440 F.3d 1317, 1324 (Fed. Cir. 2006). Evidence used to satisfy one of the Althen prongs may overlap with and be used to satisfy another prong. Id. at 1326. If a petitioner satisfies the Althen burden and meets all three prongs of the Althen test, the petitioner prevails, “unless the [government] shows, also by a preponderance of the evidence, that the injury was in fact caused by factors unrelated to the vaccine.” Knudsen v. Sec’y of HHS, 35 F.3d at 547 (brackets in original; citation omitted).

### **Medical Theory Causally Connecting Vaccination and Injury**

In this case, expert reports were filed and live testimony was taken from the experts. The first prong of the Althen test requires a petitioner to demonstrate a “medical theory causally connecting the vaccination and the injury.” Althen v. Sec’y of HHS, 418 F.3d at 1278. The Chief Special Master found that the experts agree that, “genetics play a significant role in SNHL cases.” However, accepting a general statement that it is possible for vaccines (not specific vaccines) to cause hearing loss, regarding this prong, in his Decision on Remand, the Chief Special Master wrote that, “the medical theory of how the vaccine could plausibly cause the alleged injury was not

contested; the experts agreed that an autoimmune process can result in hearing loss.”<sup>4</sup> Therefore, the petitioners met the first prong of the Althen test.

### **Proximate Temporal Relationship**

The third prong of the Althen test requires the petitioner to demonstrate, by a preponderance of evidence, “a proximate temporal relationship between the vaccination and the injury.” Althen v. Sec’y of HHS, 418 F.3d at 1278; see also Pafford v. Sec’y of HHS, 451 F.3d at 1358. The Federal Circuit emphasized the importance of a temporal relationship in Pafford v. Sec’y of HHS, when it noted that, “[w]ithout some evidence of temporal linkage, the vaccination might receive blame for events that occur weeks, months, or years outside of the time in which scientific or epidemiological evidence would expect an onset of harm.” Pafford v. Sec’y of HHS, 451 F.3d at 1358.

The Chief Special Master identified “timing,” in other words, “when did Ruby begin to lose her hearing,” as the “critical element of the Federal Circuit’s test of causation. . . .” After reviewing the available evidence, the Chief Special Master concluded in his Remand Decision that, the “petitioners failed to establish this key factual predicate – the timing of onset – which requires a finding against petitioners in Ruby’s case.”

With regard to this prong of the test, the petitioners argue that the Chief Special Master’s reversal and ultimate finding that there was not a temporal relationship between the administration of the vaccine and the onset of Ruby’s hearing loss was arbitrary and capricious. Petitioners assert that the Chief Special Master “arbitrarily and capriciously disregarded his own prior factual determination that the first indication of hearing loss for Ruby followed the December 10, 1998 vaccinations and first manifested to her parents on the night of January 1, 1999.” (emphasis in original). Indeed, in his February 9, 2005 Factual Determination, the Chief Special Master found Ruby’s parents to be “very credible” and found that “Ruby’s parents, Greg and Helen Hopkins, provided clear, convincing and consistent testimony that adequately explained any discrepancies in the record and supported their statements that Ruby’s hearing loss was not apparent until after her December 10, 1998 vaccinations.” After the factual hearing, the Chief

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<sup>4</sup> However, later in the Remand Decision, the Chief Special Master wrote that both “Dr. Raymond and Dr. Mankarious were also adamant that the vaccines involved in this case do not cause hearing loss,” specifically citing Dr. Mankarious’ statement, “[n]obody has hearing loss from those four vaccines. Not even in the medical literature.” If, in fact, the Chief Special Master accepted the testimony of respondent’s experts, Drs. Raymond and Mankarious, as reliable and more credible than the expert opinion of the petitioners, then perhaps the Chief Special Master should have concluded that the first prong of Althen was not met. Regardless, as is discussed below, petitioners fail to carry their burden and cannot substantiate their claim.

Special Master, therefore, concluded that “the parents’ testimony shall provide the factual basis for the onset of Ruby’s hearing loss,” and that the “petitioners must now provide expert witness testimony to establish whether any casual [sic] relationship exists between the vaccine and Ruby’s hearing loss.”

At the beginning of his Decision on Remand, the Chief Special Master acknowledged that he had previously issued a factual determination concluding Ruby’s parents had given credible testimony establishing that Ruby’s hearing loss was not noticed until approximately three weeks after the December 1999 vaccination, on the night of January 1, 1999. In the Remand Decision, however, when discussing the issue of timing, the Chief Special Master noted that

What looks to be a straightforward factual determination, actually turns on critical information provided by the experts. Thus the experts’ explanations and interpretations of information contained in the medical records were determinative of the issue of whether one can determine more probably or not when the hearing loss occurred in Ruby.

The Chief Special Master, therefore, based his Remand Decision on expert opinion, insisting that the credibility of the experts was “unusually important.” Among the difficult issues identified on the issue of timing, the Chief Special Master listed the following: determining hearing loss in children is extremely difficult because a child can develop normal speech with as much as a 40 decibel deficit; there was no evidence, according to one of respondent’s experts, that prior to the vaccination, Ruby had normal speech; and that in Ruby’s case, according to another of respondent’s experts, there was no specific time identified for Ruby’s hearing loss. The Chief Special Master did not accept the testimony of the petitioners’ expert, Dr. Carlo Tornatore, “because the foundational facts for Dr. Tornatore’s opinions, the appropriate timing for the onset of the hearing loss is rejected.” The Chief Special Master also dismissed petitioners’ expert, Dr. Richard T. Creagan, because he never treated children, was not an expert in genetics and vaccinology and did not consider him to be impartial. The Chief Special Master stated, “the undersigned was not impressed with Dr. Creagan and gave virtually no weight to his testimony.” In fact, on the issue of timing, the Chief Special Master indicated that Dr. Creagan’s “testimony regarding the timing of the onset was pure speculation.” Based on the expert testimony, in his Remand Decision, the Chief Special Master, therefore, concluded that, despite his earlier factual determination, “it is clear that the ‘parents perspective’ is not a reliable determinate of when Ruby’s hearing loss began.”

In reviewing the testimony of the experts, the Chief Special Master turned his attention primarily to petitioners’ expert, Dr. Tornatore, and respondent’s expert, Dr. Mankarious, having dismissed petitioners’ expert, Dr. Creagan, from his consideration. Although impressed by the testimony of respondent’s expert, Dr. Raymond, the Chief Special Master relied most heavily on the testimony of Dr. Mankarious, whose testimony he found “persuasive.” The Chief Special Master found significant credibility gaps

between petitioner's expert, Dr. Tornatore, and respondent's expert, Dr. Mankarious. The Chief Special Master found Dr. Mankarious to have "vastly superior training, experience and knowledge," and Dr. Tornatore had a "lack of the same." The Chief Special Master concluded that, "[w]hat is clear from Dr. Mankarious'[s] testimony is that the factual predicate for Dr. Tornatore's opinion was not factual, but consisted of snippets of information put forth as facts," and "Dr. Tornatore had neither the requisite knowledge nor experience to determine whether the snippets of information fit together to form a true picture or whether they were pieces of a puzzle that will never fit together." The Chief Special Master, therefore, stated that he "accepts Dr. Mankarious' discussion and explanation of all aspects of hearing loss over Dr. Tornatore's."

As described in the Chief Special Master's Remand Decision, the petitioner's expert, Dr. Tornatore, pointed to hearing tests performed in January 1999, following Ruby's immunizations, that confirmed hearing loss, but which identified Ruby's expressive and acquired language as normal. Dr. Tornatore then turned to language evaluations performed by three different clinicians, indicating that Ruby's ability to express herself verbally was typical of her age. Dr. Tornatore argued that this demonstrated that the hearing loss was of sudden onset because, "[i]f she had had a hearing loss for two years, it would not be typical of her age." Dr. Tornatore, concluded, based on these language tests and on the testimony of the parents, that there was a temporal relationship between the vaccine and the onset of hearing loss.

The Chief Special Master also relied on statements by both Dr. Mankarious and Dr. Tornatore that it is possible to have hearing loss and still develop normal speech, and statements by Dr. Raymond, that "there is no objective evidence that [Ruby] had normal hearing prior to vaccination and her abilities including speech reading present by the time of evaluation suggest a longer period of deterioration." The Chief Special Master also noted that, Dr. Raymond had written in his report that, "the coincidental discovery of her [Ruby's] hearing loss in the month following her second vaccination does not demonstrate that it was causal."

Directing attention, for the moment, solely to the question of timing, the third prong of the Althen test, the court finds that the Chief Special Master's conclusions in his Decision on Remand are not justified based on the record. In his Remand Decision, only as a brief historical note, the Chief Special Master acknowledges that in the earlier fact finding he had concluded that the third Althen prong was established based on the "parent's credible testimony." Subsequently, in the Decision on Remand, the Chief Special Master concluded, "relying heavily upon the testimony of Drs. Mankarious and Raymond [respondent's experts], the undersigned finds that the onset of Ruby's hearing loss is unknown. Accordingly, Ruby failed to establish the critical temporal relationship between their<sup>5</sup> hearing loss and immunizations. . . ."

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<sup>5</sup> Despite the remand, the Chief Special Master continued to refer to the two children, Ruby and Finn, together. Especially with respect to the issue of timing, the two cases of children of different ages present different factual profiles.

There are no contemporary medical records and Ruby was not tested for hearing loss prior to receiving her immunizations. Moreover, the experts seemed to agree, as pointed out by the Chief Special Master, that it is difficult to detect hearing loss in a young child and that a child can have mild hearing loss and still develop normal speech. The only contemporaneous information in the record regarding the timing of Ruby's hearing loss is the testimony of the parents, found credible by the Chief Special Master, as occurring, "after receiving the December 10, 1998 vaccinations." In fact, the Chief Special Master never discredits the parents in his Decision on Remand. The Chief Special Master chose to rely on speculation by the experts rather than observation by the parents. Although the Chief Special Master discredited Dr. Tornatore by pointing out that even an attentive parent could miss "moderate loss of function," in fact, the Chief Special Master found the parents did identify the "loss of function" and previously accepted their version of the timing. Not one of the experts could do other than theorize to establish more precise timing. The experts' speculation of how difficult it was to establish timing in Ruby's case did not trump the actual testimony and observations of the "credible" parents in this record. Even though Dr. Mankarious stated, "No. You can't state that the hearing loss was identified at a specific time," he also acknowledged that

I would certainly concur that Ruby's hearing loss was probably precipitously worse three weeks after the vaccine based on her history and what her father noticed. But that doesn't mean that she did not have pre-existing hearing loss.

As to the issue of timing, the third prong of the Althen test, the court finds the Chief Special Master erred when he reversed himself.

### **Logical Sequence of Cause and Effect**

The second prong of the Althen test requires petitioners to demonstrate "a logical sequence of cause and effect showing that the vaccination was the reason for the injury" by a preponderance of the evidence. Althen v. Sec'y of HHS, 418 F.3d at 1278; see also Pafford v. Sec'y of HHS, 451 F.3d at 1355. The relationship between the various prongs of the Althen test can be complex. In Capizzano v. Sec'y of HHS, the United States Court of Appeals for the Federal Circuit noted:

There may well be a circumstance where it is found that a vaccine can cause the injury at issue and where the injury was temporally proximate to the vaccination, but it is illogical to conclude that the injury was actually caused by the vaccine. A claimant could satisfy the first and third prongs without satisfying the second prong when medical records and medical opinions do not suggest that the vaccine caused the injury, or where the probability of coincidence or another cause prevents the claimant from proving that the vaccine caused the injury by preponderant evidence.

Capizzano v. Sec'y of HHS, 440 F.3d at 1327.

In his Remand Decision, the Chief Special Master also found that petitioners had failed to establish the logical sequence of cause and effect for Ruby. On this issue, the Chief Special Master once again relied heavily on a balancing of expert testimony. The Chief Special Master found petitioners' expert, Dr. Tornatore, to lack credibility, paid less attention to petitioners' expert, Dr. Creagan, but found respondent's experts, Drs. Raymond and Mankarious, significantly more credible. Such a determination as to the credibility of the experts is within the purview of the Chief Special Master, who, when determining entitlement to compensation, must weigh expert testimony on causation, since the Vaccine Act states, "[t]he special master or court may not make such a finding based on the claims of the petitioner alone, unsubstantiated by medical records or by medical opinion." 42 U.S.C. § 300aa-12(a). Direct proof, however, is not required. See Althen v. Sec'y of HHS, 418 F.3d at 1280.

Petitioners argue that "the vaccinations were the reason for the injury" and that the "[p]etitioner ha[d] normal hearing prior to vaccination." Petitioners also argue that the Chief Special Master incorrectly "faulted petitioner for failing to meet the requirements of Prong II (logical sequence of cause and effect)," when, in fact, the petitioners "have shown a logical sequence of cause and effect," showing that the vaccinations were the reason for the injury.

In Capizzano, the United States Court of Appeals for the Federal Circuit found, "[a] logical sequence of cause and effect' means what it sounds like – the claimant's theory of cause and effect must be logical. Congress required that, to recover under the Vaccine Act, a claimant must prove by a preponderance of the evidence that the vaccine caused his or her injury. 42 U.S.C. §§ 300aa-11(c)(1) – 13(a)(1)." Capizzano v. Sec'y of HHS, 440 F.3d at 1326. The logical sequence can be supported by reputable medical or scientific explanation, or otherwise stated, evidence in the form of scientific studies or expert medical testimony. See Althen v. Sec'y of HHS, 418 F.3d at 1278 (quoting Grant v. Sec'y of HHS, 956 F.2d at 1148); Devonshire v. Sec'y of the HHS, 76 Fed. Cl. 452, 454 (2007). In order to prevail, the petitioner must show "that the vaccine was not only a but-for cause of the injury but also a substantial factor in bringing about the injury." Althen v. Sec'y of HHS, 418 F.3d at 1278 (quoting Shyface v. Sec'y of HHS, 165 F.3d at 1352-53).

The Chief Special Master described petitioners' case as relying on the testimony of petitioners' expert, Dr. Tornatore, when he tried to link Ruby's autoimmune reaction, which resulted in hearing loss, to an environmental trigger or cue, in Ruby's case, the vaccine administered three weeks earlier. As stated by the Chief Special Master, "[t]he need for an environmental trigger was a key component of Dr. Tornatore's opinion – it was the core of Dr. Tornatore's logical sequence of cause and effect linking the vaccines to Ruby's and Finn's hearing loss." Dr. Tornatore himself described the genetic disposition plus an environmental trigger as "a background curve for all of my thinking."

In his Remand Decision, the Chief Special Master described how Dr. Tornatore, citing to the medical literature, concluded that if a child with normal hearing, but with a genetic predisposition for hearing loss, receives an additional environmental trigger, that trigger can push the individual over to deafness. Although the record is not definitive, there is evidence from a treating physician, Dr. Ow, of a “hereditary hearing loss.” Moreover, both Ruby’s father and paternal grandfather have an M34T genetic variant. Ruby’s father evidenced no hearing loss, whereas the adult hearing loss attributed to his grandfather resulted from either genetics or artillery exposure.

This court does not find that Dr. Tornatore’s argument that the vaccine acted as a trigger to a genetic predisposition has been proven by a preponderance of the evidence. Petitioners’ reliance on Ruby’s father and paternal grandfather does not support the petitioners’ cause of action theory, in part, because the record contains no information as to whether either of Ruby’s forbearers received the HIB, OPV and DPT vaccinations. This triggering mechanism, proposed by Dr. Tornatore as the explanation for the hearing loss in Ruby, is not sufficiently documented to carry the petitioners’ burden by a preponderance of the evidence.

Dr. Tornatore relied on a number of medical articles, including one titled “Mitochondrial Deafness Mutations Reviewed.” Dr. Tornatore testified that the article demonstrated “if you have a mitochondrial mutation, and then there is an environmental agent that’s given, you may then become deaf . . . .” Dr. Tornatore also referred to other selections from the medical literature during his testimony, including an article titled, “How to Identify Gene-Environment Interactions,” as evidence that “environment is a critical part in determining what may happen to you depending on your genetic background.” Another article titled “Gene-Environment Interaction: A Central Concept in Multifactorial Diseases,” was used by Dr. Tornatore to conclude that, “even though you have the gene, that’s not what determines whether you’re going to have it [an illness]. What determines is if there is that gene plus something else that then pushes you over,” and that “drug intake” is a factor to which genes can act as response modifiers. Or stated otherwise, Dr. Tornatore testified: “even if you have the genetic predisposition, this diagram [in the article] shows that in some cases the environmental agent pushes you over to deafness.”

The Chief Special Master dismissed the testimony and articles cited by Dr. Tornatore as not involving the vaccines administered to Ruby. In fact, the Chief Special Master severely criticized Dr. Tornatore’s credibility on multiple grounds including Dr. Tornatore’s “straying from the facts, overstating information to support a point or subtly changing language to strengthen his position.” The Chief Special Master concluded that, “[i]n summary, Dr. Tornatore’s testimony and, thus, his credibility, is severely damaged by his advocacy, his piecemeal use of medical literature, his imprecise interpretation of the same literature and frequent use of unsupported assumptions.” The Chief Special Master also discredited petitioners’ other experts on this prong of the Althen test, based on their lack of relevant credentials and their testimony. He found

that Dr. Cregan's testimony was "unhelpful," adding "nothing" to the central issue and, that it was "not impartial" or "objective."

While rejecting the testimony of petitioners' experts, the Chief Special Master chose to rely on testimony of respondent's experts, Drs. Mankarious and Raymond. The Chief Special Master found the professional experience and testimony of respondent's experts far more relevant and credible. With regard to Dr. Tornatore's conclusions, Dr. Mankarious, respondent's expert, stated:

I find that amazing that could be proposed. I see patients all the time with genetic hearing loss and there is usually never a triggering factor. There's never an illness, there's never head trauma, there's never a vaccine, there's never an ear infection that triggers the hearing loss. The hearing loss is usually spontaneous with no known inciting event, and so that's what I see on a daily basis. Nor has there ever been a triggering agent written of in the literature for genetic hearing loss such as a connexon [sic] 26 mutation.

The Chief Special Master also cited to respondent's expert, Dr. Raymond's testimony questioning Dr. Tornatore's extrapolation of the article on mitochondrial deafness. Dr. Raymond testified that the "article is completely and specifically dealing with mitochondrial mutations," and those mutations, "are the only ones that I'm aware of specifically where an environmental trigger has been clearly demonstrated to be the cause of the hearing loss." Ultimately, the Chief Special Master found Dr. Mankarious' and Dr. Raymond's testimony to undermine the testimony of Dr. Tornatore and led him, as the fact finder, to rule in favor of the respondent on the second Althen prong.

In addition, the Chief Special Master noted that the United States Court of Appeals for the Federal Circuit has instructed special masters that "treating physicians are likely to be in the best position to determine whether 'a logical sequence of cause and effect show[s] that the vaccination was the reason for the injury.'" Capizzano v. Sec'y of HHS, 440 F.3d at 1326 (quoting Althen v. Sec'y of HHS, 418 F.3d at 1278). In this regard, Dr. Endres, Dr. Ow, Dr. Massengill and Dr. Stephan, each treating physicians for Ruby, chose not to correlate the hearing loss with the vaccines (even though suggested by the parents). The majority of these doctors in their notes specifically noted that heredity, rather than environment, was, or might be, the probable cause for Ruby's hearing deficiency. Similarly, Dr. Mankarious testified that the family history of hearing loss was indicative of a non-vaccine induced reason for Ruby's hearing loss.

The Chief Special Master also found that the medical literature presented to the court provided no evidence that the vaccines administered to Ruby caused SNHL. Moreover, both Drs. Raymond and Mankarious "were adamant that the vaccines involved in this case do not cause hearing loss." In addition, the only article which



discussed the vaccines administered to petitioner was found by the Chief Special Master to be based on a fact pattern significantly different than the one before him.

Based on all of the evidence presented, the Chief Special Master concluded that petitioners had not successfully proved a “logical sequence of cause and effect showing that the vaccination was the reason for the injury.” Althen v. Sec’y of HHS, 418 F.3d at 1278. This court has carefully reviewed the record and the decision issued by the Chief Special Master and concludes his decision regarding the second Althen prong was not arbitrary or capricious, despite his perhaps overly zealous discrediting of Dr. Tornatore. The Chief Special Master acted within his discretion by giving Drs. Raymond’s and Mankarious’ testimony greater weight than that of Drs. Tornatore or Creagan. See Whitecotton v. Sec’y of HHS, 81 F.3d 1099, 1108 (Fed. Cir.). (“Congress desired the special masters to have very wide discretion with respect to the evidence they would consider and the weight to be assigned that evidence.”), reh’g and reh’g en banc denied (Fed. Cir. 1996); Sword v. Sec’y of HHS, 44 Fed. Cl. 183, 188 (1999) (“Expert opinion testimony is just opinion, and the fact-finder may weigh and assess that opinion in coming to [his or her] own conclusions.”). The petitioners have failed to prove their case by a preponderance of the evidence in this off-Table, vaccine injury case.

### **CONCLUSION**

Upon a review of the record in the above-captioned case, including the transcript, the exhibits to the record, the filings submitted by the parties, and the decisions issued by the Chief Special Master, including the Decision on Remand, this court finds that the Chief Special Master did not err in his denial of compensation to Ruby. Accordingly, the court affirms the decision of the Chief Special Master in the case of Ruby Hopkins which denied compensation to the petitioners on behalf of Ruby.

**IT IS SO ORDERED.**

s/Marian Blank Horn  
**MARIAN BLANK HORN**  
Judge